Docket No.: DFMP-P01-480

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Thomas Herget *et al.* Confirmation No.: 1016

Application No.: 10/536,950

Filed: November 16, 2005 Art Unit: 1614

For: FORMULATIONS USEFUL AGAINST HEPATITIS C VIRUS INFECTIONS Examiner: THOMAS T.P.

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This response is filed in reply to the outstanding Restriction Requirement, mailed on September 13, 2007, in connection with the above application. The period for response has been extended to February 13, 2008, by the accompanying petition for four-month extension. A Petition for Extension of Time and the appropriate fee are being filed concurrently.

Applicants hereby elect Group VII, claims 9-18, 23, 27-35, 52-56 (all in part), *with traverse*, on the following grounds.

Applicants first traverse this Unity of Invention rejection, because the Examiner has failed to raise a valid rejection under PCT Rule 13.1. Specifically, the Restriction Requirement first divides each of the independent Claims 1, 9, and 42 four ways according to the agents listed in the Markush groups of these claims, and argues that the special technical feature shared by these groups are merely "an agent" of the Markush group. The Examiner then cites Bankit *et al.* (US 4,668,515), and argues that Bankit discloses sodium selenite, which destroys the novelty of the special technical feature - "agent."

Applicants submit that "agent" is not a common special technical features that links Groups V – VIII. Rather, it is the agents' common ability to regulate HCV production in a host that constitutes the special technical feature that links Groups V – VIII. Since Bankit at best discloses one of the agents, but fails to disclose this special technical feature (*e.g.*, method of using such agents to regulate HCV production), the Unity of Invention rejection as applied to Groups V – VIII is without basis and thus improper. Reconsideration and withdrawal of the Unity of Invention rejection under PCT Rule 13.1 are respectfully requested.

The Examiner then argues that different species of the generic invention also fail to meet the Unity of Invention rejection, and requires Applicants to elect one of the three species for prosecution. Specifically, the Examiner argues that one species of any elected invention is administration of a single agent ("species 1"), another species is administration of more than one active agents (with at least one from those recited in claims 1, 9, or 42, and at least another from those recited in claims 5, 6, 13, 14, or 50, or "species 2"), yet a third species is "any other combination" of active agents ("species 3"). The Examiner only conclusively states, without any reason or explanation, that the basis for this restriction is that "(the species) are not so linked as to form a single general inventive concept under PCT Rule 13.1."

Applicants respectfully disagree. Applicants submit species 1 (*i.e.*, using a single active agent) is not even recited in the claims. It is improper for the Examiner to artificially conjure an unnamed species within a broad genus claim, and force Applicants to limit the scope of the claimed invention to a (named or unnamed) species. Applicants note that the statutory basis for restriction practice arises under 35 U.S.C. § 121, which authorizes the patent office to require that each patent application be limited to a single invention. However, there is no basis in the statute or the rules (37 C.F.R. §§ 1.141 and 1.142) for the patent office to eliminate inventions (such as genus inventions) from consideration altogether. A genus invention is as much an invention as each species invention. Thus, when the examiner enumerates the various species inventions that Applicants are required to choose between, the Examiner is without authority to omit the examination of the generic genus invention.

Furthermore, since the relationship between the genus invention (*e.g.*, using a composition comprising at least one of the active agents of claim 1, 9, or 42) and the species 1, 2,

and 3 is necessarily that of a genus – species relationship, there is, by definition, a special technical feature (*i.e.*, the technical feature of the genus invention) linking the genus invention in claim 9 and any of the species inventions enumerated by the Examiner.

Since the Examiner has not established that the special technical feature is not novel or inventive over the prior art, this Unity of Invention rejection is without basis and legally improper. Reconsideration and withdrawal of the "species election" are respectfully requested.

However, in order to avoid the appearance of not complying with the restriction, Applicants hereby *provisionally elect, for search purposes only*, "all trans retinoic acid" recited in claim 9, with traverse (see reasons above). Presently, claims 9-11, 13-18, 23, 27-29, 31-35, and 52-56 read on the elected species.

The Examiner also requires Applicants to elect between an in vitro method and an in vivo method. Applicants hereby *provisionally elect, for search purposes only*, an in vivo method, with traverse. Presently, claims 9-18, 23, 27-35, and 52-56 read on the elected species.

Applicants elect this species with traverse, because the in vitro and in vivo versions of the claimed invention are closely related such that they share a common special technical feature (*e.g.*, regulate HCV production using a recited agent). The Examiner has not established that this common special technical feature is not novel or inventive over the prior art, thus the unity of invention requirement is met. In addition, in vitro data usually supports in vivo methods if there is an art-recognized correlation between the in vitro experiments and the in vivo disease condition. Thus, there would not be any additional search burden to examine both if either of the two is elected.

In any event, Applicants note that all Group VII claims are generic claims linking elected and non-elected species (with respect to the in vitro and in vivo methods). Pursuant to MPEP 809.04, "[i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the non-elected inventions that are linked to the elected invention by such allowed linking claim." Thus, restrictions imposed on species encompassed by generic claims must be withdrawn upon indication of an allowable generic claim (MPEP 809). In other words, upon the allowance of a

generic claim, Applicants are entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141 (MPEP 809.02(a)). Applicants note that the Examiner agrees with Applicants' position in this regard.

Furthermore, the burden is on the Examiner to examine these generic claims throughout their scope, together with any claims dependent thereon drawn to non-elected species or inventions, rather than for Applicants to limit the scope of the generic claims to conform to the scope of any species or inventions listed in a Restriction Requirement.

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Please charge any fees due or credit any overpayments to Deposit Account No. **18-1945**, from which the undersigned is authorized to draw under order no. **DFMP-P01-480**.

Dated: February 12, 2008

Respectfully submitted,

By_____

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